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Gary S. Firestein

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### **ATTACHMENT TO ADVISORY ACTION**

**3. CONT.** The applicant proposes to amend the claims to compositions comprising synoviocytes transfected with a DNA vector encoding wild type p53, wherein the synoviocytes express endogenous mutant p53 protein and wherein the composition is within a joint of a mammal. The proposed claims do not correspond to the elected subject matter for which applicant's have already received two detailed actions on the merits. Applicant's elected without traverse in the response received on 12/19/06 claims drawn to compositions comprising a nucleic acid molecule encoding a polypeptide that promotes apoptosis, and further elected without traverse the species p53 as the polypeptide that promotes apoptosis. Applicant received substantive examination on this subject matter. The proposed subject matter is in fact related to that of claims 48-49 and 54 which were newly added by the amendment received on 10/19/07, and withdrawn from prosecution in the final office action mailed on 1/9/08. A composition comprising transfected synoviocytes present in a mammalian joint is a patentably distinct invention from a composition comprising a nucleic acid formulated for administration to a joint. Transfected cells or mammalian joints comprising such transfected cells -it is unclear what exactly is being claimed in the proposed amended claims- versus nucleic acids have materially different structural, chemical, and functional properties. Further, the inventions 1) have acquired a separate status in the art in view of their different classification; 2) have acquired a separate status in the art in view of their recognized divergent subject matter; (3) require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries); (d) the prior art applicable to one invention would not likely

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be applicable to another invention; and (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph. Had the proposed claims been originally presented, they would have been subject to a restriction requirement for the reasons set forth above. Thus, entry of the proposed claims would result in a situation where all pending claims would be withdrawn, leaving no claim under examination. Note that applicant does not have the right to switch inventions during prosecution or once prosecution has closed. Therefore, applicant's proposed amendment has not been entered.

The applicant is also notified that amendments presenting only claims drawn to a non-elected invention are considered non-responsive (MPEP 821.03). Therefore, should applicant file a request for continued examination (RCE) under 37 CFR 1.114 requesting entry of the amendment filed on 4/9/08, the RCE would not meet the submission requirements of 37 CFR 1.111 as required by 37 CFR 1.114(c).

**11. cont.** Applicant's arguments are based on the proposed claim amendments which have not been entered, and as such are not persuasive in overcoming the rejections of record.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology

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center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197.

Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

*/Anne Marie S. Wehbé/*

Primary Examiner, A.U. 1633